POLICY AND COMMUNICATIONS BULLETIN
THE CLINICAL CENTER

Medical Administrative Series

M92-7 (rev.) 26 September 2000

MANUAL TRANSMITTAL SHEET

SUBJECT: Advance Directives

1. Explanation of Material Transmitted: This bulletin transmits the policy of the Clinical Center regarding the use of advance directives. The policy was reviewed by the Medical Executive Committee on 19 September 2000 and approved with changes. Of note, research subjects may now differentiate between their wishes for health care and research participation on the "NIH Advance Directive for Health Care and Medical Research Participation" form (NIH 200). The revised policy also clarifies how advance directives are charted/filed, modified or rescinded, and what to do when research subjects do not have their advance directives with them.

2. Material Superseded: MAS No. M92-7 (rev.), dated 2 September 1997

3. Filing Instructions: Informed Consent Section

   Remove: No. M92-7 (rev.), dated 2 September 1997

   Insert: No. M92-7 (rev.), dated 26 September 2000

DISTRIBUTION

Physicians, Dentists and Other Practitioners Participating in Patient Care

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BACKGROUND

People's preferences concerning their health care, research participation, and the manner in which they die are issues of great importance. Too often, when patients cannot speak for themselves, critical health care and end of life decisions are made without sufficient knowledge of their preferences. Health care professionals have a responsibility to discuss these issues with their patients so that clinical care can be provided in accord with what their patients would have wanted. At the Clinical Center, investigators have the additional responsibility of exploring and honoring their subjects' preferences regarding research participation.

PURPOSE

The purpose of this policy is to delineate staff responsibilities and procedures for informing research subjects about advance directives, to assist them in articulating their preferences regarding health care and research participation, and to honor those preferences. This policy satisfies the 1990 federal legislation, "Patient Self-Determination Act," which requires that health care institutions inform patients of their right to participate in, and direct, their health care by implementing advance directives. This policy complements Medical Administrative Series policies M87-4, "Consent Process in Research Involving Impaired Human Subjects" and M91-7, "Do Not Resuscitate (DNR) Orders and Limited Treatment Orders."

DEFINITIONS

A. *Adult Research Subject*

An adult is a person who (1) is 18 years or older, or (2) is married, or (3) has a child. The term "research subject" in this policy refers to adult patients and clinical research volunteers seen at the Clinical Center.

B *Advance Directives*

Advance directives are written documents that allow individuals to specify in advance their preferences concerning their health care and/or research participation. Advance directives go into effect when individuals are unable to make or communicate their own decisions. NIH advance directives (see section C below) and non-NIH advance directives can be changed at anytime and remain in effect unless changed or canceled by the research subject.

The two principal kinds of advance directives are the "Durable Power of Attorney for Health Care" and the "Living Will." A Durable Power of Attorney for Health Care is an advance directive in which individuals appoint an agent to make health care decisions for them in the event that they become incapable of doing so. A Living Will is an advance directive in which individuals specify which medical interventions they would want instituted, continued, withheld, or withdrawn in the event that they are in a persistent vegetative state or diagnosed with a terminal illness and are incapable of making these decisions.

C. *The Clinical Center Advance Directive for Health Care and Medical Research Participation (form NIH 200)*

The NIH Advance Directive for Health Care and Medical Research Participation form combines the essential components of a living will and a durable power of attorney for health care and research participation. Part I of the form allows research subjects to appoint a substitute decision maker (agent). Part II allows research subjects to document specific preferences they have concerning their medical research participation. Part III allows research subjects to document specific preferences they

have concerning health care; this section is similar to a living will. In contrast to living wills, however, form NIH-200 is not restricted to individuals who are terminal or in a persistent vegetative state. The NIH Advance Directive for Health Care and Medical Research Participation is designed for use only at the Clinical Center. It may, however, provide guidance as to a person's preferences when they leave the Clinical Center. This form and directions for its use may be obtained from the Clinical Center Department of Clinical Bioethics, 496-2429.

D. *Advance Directive Resource Person*

An advance directive resource person is an individual trained to provide information about, and assistance with the execution of, advance directives. Clinical Directors are responsible for assuring that an advance directive resource person is available to their institute's research subjects. Designated personnel may include physicians, nurses, social workers, physician assistants, or others.

POLICY

A. All adult research subjects will receive written information on advance directives at the time of their initial admission to the Clinical Center.

B. All adult inpatient, outpatient, and day hospital research subjects will be asked about their advance directive status during each nursing admission assessment. Outpatients who do not receive a formal nursing admission assessment will be asked about their advance directive status by a member of the research team when indicated.

C. In light of the unique research environment of the NIH, research subjects without an advance directive or with a non-NIH advance directive will be encouraged to execute an NIH Advance Directive for Health Care and Medical Research Participation (form NIH 200) to address both their research and health care preferences.

D. Research participation and the provision of care at the Clinical Center are not dependent upon the execution of an advance

directive, except for certain protocols as stipulated by an Institutional Review Board or as required by Medical Administrative Series policy M87-4, "Consent Process in Research Involving Impaired Human Subjects."

E. Advance directives (NIH and non-NIH) will be kept in the subject's chart in the Advance Directive section while on an inpatient unit and subsequently in the medical record after discharge.

F. Health care providers will be familiar with the advance directives of research subjects under their care.

G. The medically responsible physician will discuss with their research subjects the implications of their advance directives, and will honor these preferences.

H. Bioethics consultation will be obtained whenever there is disagreement, uncertainty or conflict regarding a subject's advance directive.

PROCEDURE

A. *Pre-admission*

Prior to admission, research subjects will be asked by each institute to bring existing advance directives with them to the Clinical Center.

B. *Admission to the Clinical Center*

1. Initial Admission

The admitting clerk, at the initial admission, will provide an admissions packet to research subjects. This packet contains written information on subjects' right to make decisions concerning their health care, including the right to execute an advance directive.

2. Assessment

a. the admitting nurse, as part of each admission assessment, will ask research subjects if they have an advance directive with them and, if so, whether they want it to continue in effect at the Clinical Center.

1) If the research subject has their advance directive with them and wants it to continue in effect, a copy of the advance directive is placed in the Advance Directive section of the inpatient chart by the admitting nurse.

2) If the research subject does not have their advance directive with them but wants it to continue in effect, staff will assist them in getting a copy. In the meantime, the patient will be encouraged to complete the NIH Advance Directive for Health Care and Medical Research Participation (form NIH 200). The advance directive resource persons and the Department of Clinical Bioethics are available to assist in these processes. If a copy of the previous advance directive is not in the patient's inpatient chart or medical record and the subject has not completed the form NIH 200, the subject will be considered in the category of subjects without an advance directive (see 4 through 6 below).

3) If the research subject's advance directive is in the medical record (old chart), a photocopy will be obtained for the research subject and placed in the current inpatient chart.

4) If the research subject does not have an advance directive but wants more information or assistance in executing one, clinical staff can assist them or they will be referred to an advance directive resource person.

5) If the subject does not have a written advance directive in the inpatient chart but

makes a statement to their medically-responsible physician designating their decision-maker or their preferences, this statement must be witnessed by a third party. This information will be documented by the physician and signed by the witness, recorded on the Continuation page of the NIH Advance Directive for Health Care and Medical Research Participation (form NIH 200-1), titled "Oral Advance Directive Statement" and filed in the Advance Directive section of the inpatient chart. This Continuation page may be filed alone, without NIH 200.

6) If the research subject does not have an advance directive and does not wish to execute one, and further, does not wish to orally designate their decision-maker or preferences, no further action except documentation of this is necessary.

b. the advance directive resource person is available to assist clinical staff in advising research subjects about advance directives and assisting them in obtaining and executing advance directives.

c. the individual who places the advance directive in the chart will ensure that the medically responsible physician is notified of the existence of the research subject's advance directive.

3. Reassessment

The advance directive status of all research subjects will be reassessed 1) whenever there is a significant change in the research subject's clinical status, and 2) as defined by the reassessment time frames for each specific outpatient/Day Hospital population (see Nursing Department Standards of Practice for Documentation).

C. *Documentation*

1. At each admission, the admitting nurse will document each research subject's advance directive status in the Clinical Center Medical Information System or on an approved medical record form. In addition, the advance directive resource person and/or the primary nurse will document changes in the research subject's advance directive status as they occur.

2. Upon completion of the NIH Advance Directive for Health Care and Medical Research Participation (form NIH 200), the top copy will be filed in the Advance Directive section of the active medical record. Copies will be distributed as designated on the form. The Medical Records Department will maintain the advance directive in the Advance Directive section of the medical record after discharge.

3. Non-NIH advance directives will also be filed in the Advance Directive section of the chart during the admission and maintained in the medical record after discharge.

4. Valid advance directives can be revised or replaced by a subject who wants to change his or her directive. The new advance directive should replace the old one in the patient's chart. If a research subject who has a valid advance directive decides that he or she no longer wants any advance directive to remain in effect, this should be explicitly documented. Clinical Center staff will assist that subject in indicating and dating this change on the NIH Advance Directive Continuation page and filing this in the medical record in the Advance Directive section. Copies of the old advance directive should be removed from the chart.

D. *Special Concerns*

The advance directive process may raise ethical or legal issues that require more in-depth consideration. These may include questions about the interpretation and application of advance directives already in existence or the cognitive ability of the research subject to execute an advance directive. In addition, health care providers should be aware that individuals unable to execute an advance directive for cognitive reasons may also

be unable to consent to research participation (see Medical Administrative Series policy M87-4). Consultation on these issues is available through the Department of Clinical Bioethics (496-2429 or 435-4971).

EDUCATION

A. *Advance Directive Resource Personnel*

The Clinical Center, through the Department of Clinical Bioethics, will provide formal training, educational materials, and on-going instruction and support for Clinical Center staff.

B. *Community Education*

At the direction of the Medical Executive Committee, the Clinical Center Ethics Committee, Clinical Center Communications Office, and other appropriate departments will coordinate community outreach educational activities on advance directives.

SUPERVISION

Responsibility for this policy's implementation, and evaluation rests with the Medical Executive Committee, with the assistance of its various subcommittees, most notably the CC Ethics Committee.